Significant Analysis
for Rule Concerning Newborn Screening,
WAC 246-650-246

Briefly describe the proposed rule.

Amend WAC 246-650-010 to add a definition of cystic fibrosis. Add cystic fibrosis to the disorders listed in Section -020 that are to be detected through the Department of Health (DOH) newborn screening program. And, provide a timeline for DOH to implement screening for cystic fibrosis in Section -030.

Is a Significant Analysis required for this rule?

Yes, adding cystic fibrosis to the screening panel in Section -020 significantly amends policy.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

RCW 70.83.010. Declaration of policy and purpose.
It is hereby declared to be the policy of the state of Washington to make every effort to detect as early as feasible and to prevent where possible phenylketonuria and other preventable heritable disorders leading to developmental disabilities or physical defects.

RCW 70.83.020. Screening tests of newborn infants.
It shall be the duty of the department of health to require screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders leading to mental retardation or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

Cystic fibrosis is a serious, life shortening disorder. Numerous studies have demonstrated that children detected through newborn screening and entered into comprehensive cystic fibrosis clinical care have significantly improved health outcomes when compared to children who are detected after they develop symptoms of the disorder. The State Board of Health and DOH have held meetings with cystic fibrosis experts and with a specially convened Cystic Fibrosis Newborn Screening Advisory Committee comprised of a broad range of interested parties including payers, professional organizations, parents, and medical specialists. These groups have concluded, and the Board has concurred, that the evidence supports adding cystic fibrosis to the screening panel.
Adopting these amendments will allow screening to be conducted on the same small sample of dried blood that is currently collected from each newborn and submitted to DOH for screening to detect the other nine disorders that are in the current rule. Absent rule making, universal screening will not occur and children born with cystic fibrosis will not be assured of access to the benefits available through early detection and treatment.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

DOH staff, including the DOH economist, has prepared an economic analysis (see attached) which concludes that early detection and treatment of cystic fibrosis through newborn screening will return $5.40 in benefits for each dollar spent.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

The proposed rule does not place additional requirements on anyone outside of DOH (which is required to add cystic fibrosis testing to the screening panel). Screening will be conducted from the same small blood specimen that is already required to be sent to DOH for screening to detect the nine disorders on the current panel (no additional blood will be required).

Alternatives are: (1) continue the current status of detecting children with cystic fibrosis after symptoms appear and significant damage has occurred and (2) encourage birthing providers to seek screening on their own. This would add significantly to the costs, decrease the reliability of the testing, decrease the likelihood that affected infants would be linked to appropriate clinical care in time to realize the benefits of early detection, and thus increase the number of infants with cystic fibrosis who would "fall through the cracks" and not receive the benefits available through early detection and treatment.

As described above, the possible alternatives do not achieve the objective of assuring that every infant born in our state is screened for cystic fibrosis shortly after birth and that those found to be affected are linked to treatment that can significantly reduce adverse outcomes of the disorder.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.